



# LANTOS-HYDE UNITED STATES GOVERNMENT MALARIA STRATEGY

2009–2014



APRIL 25, 2010



PRESIDENT'S MALARIA INITIATIVE



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MALARIA STRATEGY**

**2009–2014**

## GLOBAL HEALTH INITIATIVE – THE CONTEXT

*“Last summer, the Congress approved the Lantos-Hyde U.S. Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act – legislation that I was proud to co-sponsor as a U.S. Senator and now carry out as President. But, I also recognize that we will not be successful in our efforts to end deaths from AIDS, malaria, and tuberculosis unless we do more to improve health systems around the world, focus our efforts on child and maternal health, and ensure that best practices drive the funding for these programs.”*

– President Barack Obama, announcing the Global Health Initiative, May 5, 2009

Through the Global Health Initiative (GHI), the United States will invest \$63 billion over six years to help partner countries improve health outcomes, with a particular focus on improving the health of women, newborns and children. The GHI is a global commitment to invest in healthy and productive lives, building upon, and expanding, the U.S. Government’s successes in addressing specific diseases and issues. Addressing wide-ranging health needs in partnership with governments, communities, and other partners represents an ambitious agenda that can be met only if we work together, aligned toward common goals, with a commitment to improve fundamentally the way we do business.

The GHI aims to maximize the impact the United States achieves for every health dollar it invests, in a sustainable way. The GHI’s business model is based on: implementing a woman- and girl-centered approach; increasing impact and efficiency through strategic coordination and programmatic integration; strengthening and leveraging key partnerships, multilateral organizations, and private contributions; encouraging country ownership and investing in country-led plans and health systems; improving metrics, monitoring and evaluation; and promoting research and innovation.

The GHI will build on the United States’ accomplishments in global health, accelerating progress in health delivery and investing in a more lasting and shared approach through the strengthening of health systems.

## EXECUTIVE SUMMARY

Malaria prevention and control is a major U.S. foreign assistance objective and is a core component of a comprehensive U.S. Government (USG) **Global Health Initiative** (GHI), announced in May 2009 by President Barack Obama to reduce the burden of disease and strengthen communities around the world. The 2008 Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act (Lantos/Hyde Act) authorizes up to \$5 billion in USG funding for malaria prevention and control for the period FY2009–2013. This Act calls for the development of a comprehensive, multiyear USG strategy to combat malaria globally and strengthen the capacity of the United States to be an effective leader of international efforts to reduce the burden of malaria.

For the purposes of planning, the proposed **Lantos-Hyde United States Government Malaria Strategy** (USG Malaria Strategy) reflects a six-year horizon (2009–2014) consistent with the duration of the Global Health Initiative. An evaluation of the activities under the USG Malaria Strategy will take place in the latter half of 2015 to assess progress on activities undertaken through 2014.

The **Strategic Vision** is that the United States will continue to provide global leadership in reducing preventable malaria deaths to near zero by 2015 and strive toward the ultimate goal of eradication.

As part of the GHI, the USG Malaria Strategy for 2009–2014 proposes an expanded approach to USG-supported malaria control efforts directed at:

- **Achieving Africa-wide impact**, by halving the burden of malaria (morbidity and mortality) in 70 percent of at-risk populations in sub-Saharan Africa (approximately 450 million people), thereby removing malaria as a major public health problem and promoting economic growth and development throughout the region;
- **Limiting the spread of antimalarial multi-drug resistance** in Southeast Asia and the Americas;
- Increasing emphasis on **strategic integration** of malaria prevention and treatment activities with maternal and child health, HIV/AIDS, neglected tropical diseases, and tuberculosis programs, and on **multilateral collaboration** to achieve internationally-accepted goals;
- Intensifying present efforts to **strengthen health systems** and strengthen the capacity of host-country workforces to ensure sustainability;
- Assisting host countries to revise and update their National Malaria Control Strategies and Plans to reflect the declining burden of malaria, and **linking programming of USG malaria control resources to those host-country strategies**; and
- Ensuring a **woman-centered approach** for malaria prevention and treatment activities at both the community and health facility levels, since women are the primary caretakers of young children in most families and are in the best position to help promote healthy behaviors related to malaria.

This USG Malaria Strategy for 2009–2014 also includes important elements of operational research in support of malaria prevention and control efforts that complement the malaria research activities funded by the Department of Health and Human Services (HHS) and executed through the HHS's National Institutes of Health and the Centers for Disease Control and Prevention and by the Department of Defense. This Strategy does not deal with the basic and clinical research being conducted by other USG agencies.

## BACKGROUND

Malaria is a preventable and treatable disease. As recently as 2005, it was estimated to cause between 300 and 500 million illnesses and nearly one million deaths each year. More than 90 percent of these illnesses and deaths occurred among children under five years of age in sub-Saharan Africa. In Asia and the Americas, malaria causes many fewer severe illnesses and deaths, but antimalarial drug resistance is a serious and growing problem. Furthermore, evidence suggests that some drug-resistant strains of malaria have been imported to East Africa from Asia.

The landscape of global malaria control has changed dramatically in the last decade. Three major initiatives have been established to control malaria: the U.S. President's Malaria Initiative (PMI); The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund); and the World Bank Malaria Booster Program. The Roll Back Malaria (RBM) Partnership, created in 1998, has helped to coordinate and harmonize partners' efforts, including a striking increase in private-sector contributions.

As a result, funding for global malaria control has increased sharply since 2000, reaching about \$1.5 billion in 2007. According to the RBM Global Malaria Action Plan, in the 109 malarious countries or territories where malaria is endemic, the total costs for malaria prevention and treatment activities and program strengthening worldwide are estimated to range from \$6 to \$7 billion annually for the next 10 years. Africa accounts for about one-half of those costs.

**The President's Malaria Initiative (2005–2010):** In June 2005, the U.S. Government announced a new five-year, \$1.2 billion initiative to rapidly scale up malaria prevention and treatment interventions in 15 high-burden countries in sub-Saharan Africa. The initiative is led by the U.S. Agency for International Development (USAID) and implemented together with HHS's Centers for Disease Control and Prevention (CDC). The goal of this initiative is to reduce malaria-related mortality by 50 percent across the 15 focus countries through a rapid scale-up of four proven malaria prevention and treatment measures: insecticide-treated mosquito nets (ITNs); indoor residual spraying (IRS) of insecticides; artemisinin-based combination therapy (ACTs); and intermittent preventive treatment of pregnant women (IPTp).

Selection of the 15 focus countries was based on their malaria burden, the presence of technically sound national malaria control policies, willingness to partner with the United States, and a Global Fund malaria grant. The initiative, which began in 2006, was initially expected to cover a population of 170 million but is now covering 270 million residents in the 15 PMI focus countries (see Table 1 below).

**Table 1 – President's Malaria Initiative Focus Countries**

Fiscal Year (FY)	Budget	Focus Countries
2006	\$30 million <sup>1</sup>	Round 1: Angola, Tanzania, Uganda
2007	\$135 million <sup>2</sup>	Round 2: Malawi, Mozambique, Rwanda, Senegal (in addition to Round 1 countries)
2008	\$300 million <sup>3</sup>	Round 3: Benin, Ethiopia (Oromia Region), Ghana, Kenya, Liberia, Madagascar, Mali, and Zambia (in addition to Round 1 and Round 2 countries)
2009	\$300 million	All 15 PMI focus countries
2010	\$500 million	All 15 PMI focus countries
<b>TOTAL: \$1.265 billion</b>		
<p>1. In addition, Angola, Tanzania, and Uganda also used \$4.2 million in FY05 funds for malaria activities.</p> <p>2. This total does not include \$25 million of additional FY07 funding, of which \$22 million was used for malaria activities in the 15 PMI focus countries. In addition, Malawi, Mozambique, Rwanda, and Senegal used \$11.9 million in FY06 funds for malaria activities as allocated by the U.S. Global Malaria Coordinator.</p> <p>3. Benin, Ethiopia (Oromia Region), Ghana, Kenya, Liberia, Madagascar, Mali, and Zambia also used \$23.6 million of FY06 and \$42.8 million of FY07 funding (of which \$2.8 million was included in the \$25 million additional FY07 funding) as allocated by the U.S. Global Malaria Coordinator.</p>		

**Progress to date:** As agreed upon when PMI was launched in 2005, and as a member of the RBM Partnership, PMI does not try to attribute increases in coverage of malaria interventions or reductions in malaria morbidity and mortality to PMI-supported efforts alone. Instead, PMI measures progress toward achieving national and international goals and targets that result from the combined efforts of host country governments and other partners involved in malaria control in that country.

In collaboration with national malaria control programs and other major donors, major progress has been made in scaling up malaria prevention and treatment measures across the 15 PMI focus countries. Significant reductions in malaria-related morbidity and 20–30 percent reductions in all-cause childhood deaths (to which malaria is a major contributor) are already being reported from six countries: Ghana, Kenya, Rwanda, Senegal, Tanzania, and Zambia. For example, in Rwanda, (where USAID has been providing funding for malaria activities since 2002 and PMI “jump start” funds beginning in FY2006), a 2008 national survey showed that the frequency of malaria parasitemia fell to less than 3 percent and that under-five childhood mortality fell by 32 percent when compared with 2005; during the same time period, the proportion of children sleeping under an ITN has risen nearly four-fold to 57 percent. In Senegal, there has been a 29 percent reduction in under-five mortality over the same time frame, while household ownership of at least one ITN rose from 36 percent to 60 percent. In Zambia, national survey data showed that between 2006 and 2008 there was a 53 percent decline in the frequency of malaria infection and a 68 percent decline in severe anemia in children under five, and between 2001 and 2007, a 29 percent reduction in deaths in children under five. District-level impact has also been reported in several other countries where ITN usage has already reached high levels and/or large-scale IRS is underway.

## PRESIDENT'S MALARIA INITIATIVE (2009–2014)

The 2008 Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act (Lantos/Hyde Act) authorizes up to \$5 billion in U.S. Government (USG) funding for malaria prevention and control. This Act provides for the continuation of support to the 15 PMI focus countries and an expansion to other endemic countries. The Act also calls for the development of a comprehensive multi-year USG malaria strategy.

In May 2009, President Obama announced the USG Global Health Initiative (GHI), a six-year, \$63 billion commitment to global health. It includes \$51 billion to build on the progress made in recent years against malaria, HIV/AIDS, and tuberculosis, together with \$12 billion for maternal and child health and neglected tropical diseases programs. This new initiative places renewed USG emphasis on health systems strengthening, program integration, and a woman-centered approach to health development.

### Guiding Principles

Malaria prevention and control is a major U.S. foreign assistance objective and is a component of a comprehensive USG global health strategy to reduce the burden of disease and strengthen communities around the world. Full funding of the Lantos/Hyde Act will greatly contribute to broader USG health objectives: reducing global under-five mortality, reducing global maternal mortality, strengthening health systems, and promoting economic growth in Africa.

### Vision

The United States will provide global leadership in reducing preventable malaria deaths to near zero by 2015 and in striving toward the ultimate long-term goal of eradication.

Building on the progress and experiences of PMI during the past four years, together with the new approach to international health efforts outlined in the USG Global Health Initiative, the USG Malaria Strategy sets out the following goal and objectives for the period 2009–2014:

### Goal

Work with partners to halve the burden of malaria (morbidity and mortality) in 70 percent of the at-risk populations of sub-Saharan Africa, thereby removing malaria as a major public health problem and promoting development throughout the African region.

### Objectives

- ***In sub-Saharan Africa***, with full funding over the next five years, the USG will work with National Malaria Control Programs (NMCPs) and partners to accomplish the following:
  - *By 2015, achieve a 70 percent reduction in malaria burden (morbidity and mortality) in the original 15 PMI focus countries, when compared with the PMI baseline established in 2006/2007;*
  - *Expand malaria control efforts to reach large areas of the Democratic Republic of the Congo (DRC) and Nigeria and up to seven additional high burden countries, achieving a 50 percent reduction in malaria burden (morbidity and mortality) in at-risk populations when compared with a 2009–2010 baseline (to be established for these countries). Nigeria and DRC are the two highest burden countries in Africa and account for half of all malaria cases on the continent. The selection of the seven additional countries will be based on population, malaria burden, health infrastructure, and availability of other donor funding.*

Altogether, the increased funding will allow USG-supported malaria prevention and treatment measures to be expanded to reach approximately 450 million people, or about 70 percent of the at-risk populations of sub-Saharan Africa.



- ***In Southeast Asia and the Americas***, where antimalarial multidrug-resistance is one of the greatest threats to global malaria control, the USG will work with NMCPs and partners to strengthen efforts to contain the spread of multidrug resistant *Plasmodium falciparum* malaria. This will be accomplished by:
  - Supporting well-functioning antimalarial drug resistance surveillance networks in each country in the region;
  - Establishing national systems to monitor the quality of antimalarial drugs as a means of preventing the introduction and dissemination of sub-standard or counterfeit drugs, which contribute to increased drug resistance; and
  - Contributing to a further reduction in the level of transmission of *P. falciparum* malaria and the number of reported cases in the Greater Mekong Region and the Amazon Basin, with a goal of elimination of malaria in these areas by 2020.

***Globally, these efforts will:***

- Integrate malaria prevention and treatment activities with maternal and child health efforts, and other major health programs, including HIV/AIDS, neglected tropical diseases, and tuberculosis;
- Build the capacity of host-country health systems and workforces, especially related to critical health systems bottlenecks, such as supply chain management, disease surveillance and reporting, monitoring and evaluation, and laboratory diagnostic services;
- Assist countries to revise and update their national malaria control strategies and plans, as appropriate, to reflect the declining burden of malaria, and link programming of USG malaria control resources to those host-country documents; and
- Ensure a women-centered approach to malaria prevention and treatment activities at both the community and health facility levels, since women are the major caretakers of young children who, along with pregnant women, are most vulnerable to the effects of malaria infections.

## **Funding Availability**

The population targeted in Africa will be calibrated to the funding available through the GHI. If less than full funding is appropriated under this program, then the expected reductions in malaria burden, including in children, will be proportionally reduced.

## **Strategic Principles**

The USG Malaria Strategy for 2009–2014 is guided by many of the same general principles in planning, implementing, and evaluating its malaria control activities that were established when PMI was initially launched:

- a) Work within existing national malaria control strategies and plans and strengthen the capacity of national institutions and professionals to address the challenges of malaria control and build country ownership and sustainability;
- b) Maintain sufficient flexibility and remain responsive to the ever-changing nature of malaria and tailor efforts to the local epidemiologic setting, including efforts to substantially increase the level of integration of malaria activities with maternal and child health, HIV/AIDS, tuberculosis, and neglected tropical diseases;
- c) Design and implement activities in a way that will achieve malaria control objectives at the same time that it builds the capacity of host country systems and workforces, while assessing the impact of these efforts on a country-by-country basis;
- d) Utilize a woman-centered approach and promote healthy behaviors related to malaria in families;
- e) Remain vigilant to emerging threats, such as drug and insecticide resistance, through rigorous monitoring and surveillance;
- f) Promote an integrated and sustainable approach to malaria prevention and control, emphasizing the combined use of antimalarial drugs, vector control measures, behavior change interventions, and as they become available,

new tools and strategies that have demonstrated efficacy, have been recommended by the World Health Organization (WHO), and have been locally endorsed;

- g) Focus interventions on high-risk populations, while scaling up to universal coverage;
- h) Coordinate closely with other multilateral and bilateral institutions and donors and their associated working groups and task forces within the broader RBM Partnership, such as the Global Fund, World Bank, WHO, and UNICEF, to ensure that investments are complementary;
- i) Expand and leverage public-private partnerships;
- j) Coordinate monitoring and evaluation activities with NMCPs and other partners to track progress toward targets using internationally-accepted indicators and to provide data for timely decision-making; and
- k) Conduct operational research that helps overcome implementation bottlenecks, contributes to the scale-up of malaria control activities, and identifies the most cost-effective mix of currently recommended interventions under different malaria transmission settings.

## Strategy for Sub-Saharan Africa

To achieve its goal of reduction in malaria-related deaths in Africa, the USG Malaria Strategy will continue to focus on countrywide scale-up of a combination of four proven and highly effective interventions in each of the target countries:

- Long lasting insecticide-treated nets (LLINs);
- Indoor residual spraying (IRS) with insecticides;
- Intermittent preventive treatment of pregnant women (IPTp), where appropriate; and
- Treatment with artemisinin-based combination therapies (ACTs), ideally based on a laboratory diagnosis of malaria.

Insecticide-treated nets: The USG supports the RBM framework for LLIN distribution. This is a multipronged approach to scale up ownership and usage of nets through free distribution during national or sub-national campaigns, free or highly subsidized distribution through antenatal and child health clinics, together with strengthening capacity of the private sector to provide subsidized and unsubsidized LLINs at the lowest possible market price. This approach is intended to produce a rapid scale-up of net coverage, ensuring equity for poor, hard-to-reach, and vulnerable populations at the same time that it promotes sustainability. In line with goals set forth by RBM, the USG will support universal coverage with LLINs where this is national policy.

Indoor residual spraying: Between 2005 and 2009, PMI supported the introduction or extension of IRS in all 15 PMI focus countries. PMI-funded IRS activities focused on areas with seasonal transmission (where transmission is limited to certain months of the year and is absent or falls to very low levels during other months). This provides year-round protection with a single round of spraying, rather than focusing on areas with year-round transmission where two or more rounds of spraying are required for full protection. Only WHO-approved insecticides will be procured and used for USG-supported spraying programs. To mitigate the spread of insecticide resistance, USG vector control efforts will support a regular rotation of insecticides from different classes. In addition, all USG-supported IRS will continue to follow required environmental assessment procedures as described in the Code of Federal Regulations, Part 216 (22 CFR 216).

Malaria in pregnant women: The USG supports implementation of the WHO-RBM “Strategic Framework for Malaria Control during Pregnancy in Africa.” This recommends a three-pronged approach to reduce the burden of malaria infection among pregnant women in areas with moderate to high-level transmission in the African Region: (1) IPTp, which involves the administration of a full, curative treatment with sulfadoxine-pyrimethamine (SP), an antimalarial drug, at pre-defined intervals during pregnancy; (2) ITNs; and (3) effective treatment of malarial illnesses among pregnant women. Since more than 70 percent of pregnant women in Africa attend antenatal clinics at least once during their pregnancy, the provision of IPTp and ITNs during these clinic visits is both feasible and attractive.

HIV infection diminishes a pregnant woman’s ability to control *P. falciparum* infections. Consequently, the USG strongly supports efforts to improve diagnosis and prompt and effective treatment as well as prevention of malaria

infections during pregnancy as part of a comprehensive package of HIV/AIDS care. This will be done in coordination with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in those countries where both programs are working.

Effective diagnosis and treatment of malaria: Timely and accurate diagnosis of malaria is key to the effective management of malaria infections and the prevention of severe malaria and malaria-related deaths. With the spread of antimalarial drug resistance and adoption of newer and more expensive combination therapies, accurate diagnosis has become even more important as a means of targeting malaria therapy and reducing reliance on presumptive treatment of all febrile patients with antimalarial drugs.

The USG Malaria Strategy will continue to support the WHO recommendation that countries experiencing resistance to their current antimalarial drug monotherapies adopt ACTs as first-line treatment for uncomplicated malaria. The USG will provide technical assistance to ministries of health and NMCPs to ensure smooth and effective implementation of newly adopted ACT treatment policies. This includes assistance on forecasting, procurement, testing and monitoring the quality of antimalarial drugs, regulatory response to substandard drugs, distribution, storage and inventory management, and post-marketing surveillance. Since 50 percent or more of all patients with suspected malaria in Africa seek treatment outside the formal health care system, the USG will also support efforts to understand the role of the private sector in malaria treatment and improve provision of appropriate and safe antimalarial drug regimens through private sources. In addition, the USG will support regular monitoring of antimalarial drug resistance to ensure early detection of reduced sensitivity of malaria parasites to artemisinin drugs and the ACTs.

New tools: A number of new malaria control tools are under development. One of these, intermittent preventive treatment in infants (IPTi), has received recent provisional approval from WHO. This strategy involves the administration of an antimalarial drug (usually SP) three times during infancy at the time of routine vaccinations. The strategy will be limited to countries with continuing moderate or high malaria transmission and moderate or lower levels of SP resistance. Once the strategy receives formal approval from WHO, the possibility of IPTi scale-up in countries will be considered.

Although individual control measures may have a significant impact on malaria illnesses and deaths in the short term, lasting and sustainable reductions in malaria burden will depend on an integrated approach using a combination of the above prevention and treatment measures and strengthening health systems and building capacity for local ownership.

## **Strategy for Southeast Asia and South America**

Levels of malaria transmission in Southeast Asia and South America are much lower than in sub-Saharan Africa. Although malaria is responsible for considerable illnesses in these regions, deaths due to malaria are much less common. Because of the lower levels of transmission, immunity to malaria is not acquired during childhood and all age groups and both men and women are at risk of disease. National malaria control programs in these two regions are generally quite strong and are able to meet most of the commodities and services needs for malaria prevention and control.

The spread and intensification of antimalarial drug resistance represents the single most serious challenge to malaria control in Asia and the Americas. In the Mekong Region of Southeast Asia, strains of *P. falciparum* have already developed resistance to chloroquine, SP, and mefloquine, and the recent reports of resistance to artemisinin are particularly alarming. There is also evidence to suggest that in the past Southeast Asia may have been the major source of drug-resistant strains of malaria parasites in East Africa. In the Amazon Basin, high-level resistance to both chloroquine and SP is already present, and there is evidence of early mefloquine resistance, although ACTs remain effective.

The USG has taken a regional approach to supporting malaria control activities in Asia and the Americas, although it also supports activities at the country level. During the last ten years, USAID in collaboration with CDC assisted NMCPs in strengthening antimalarial drug resistance surveillance and updating and implementing national malaria treatment policies based on ACTs, as recommended by WHO. All eight of the countries making up the Amazon Basin of South America and five of the six countries in the Mekong Region of Southeast Asia have now adopted ACTs as their first-line drugs for the treatment of *falciparum* malaria.

The challenge now is to sustain routine monitoring of antimalarial drug resistance to detect early any loss in efficacy of the first- and second-line drugs. With the spread of drug resistance, accurate laboratory-based diagnosis with microscopy

or rapid diagnostic tests has become even more important as a means of targeting malaria therapy. Counterfeit or substandard antimalarial drugs are being encountered with increasing frequency as drug resistance drives the cost of malaria treatments higher. This problem is particularly serious in Southeast Asia, where extremely sophisticated counterfeits of several artemisinin drugs and ACTs have been detected. Through its implementing partners, the USG Malaria Strategy will continue to work with the WHO, the U.S. Food and Drug Administration (FDA), host country governments and other U.S. and international groups to ensure the quality of drugs purchased from recommended manufacturers and to establish or strengthen national capabilities for antimalarial drug quality testing.

Given the relatively low levels of malaria transmission in Southeast Asia and South America, when compared with sub-Saharan Africa, targeted efforts in these areas can reduce the spread of antimalarial drug resistance and may ultimately lead to national and/or regional elimination of malaria. For this reason, the USG will support focused activities, such as active case detection and treatment, as well as outreach to hard-to-access groups to reduce further the risk of malaria transmission in the Mekong Region and Amazon Basin.

## THE USG MALARIA STRATEGY'S LONG-TERM VISION (2015–2040)

The USG Malaria Strategy for 2009–2014 will directly contribute to the RBM Partnership's Global Malaria Action Plan, which aims to achieve and sustain reductions in worldwide malaria deaths and illnesses over the next 10 to 15 years. The long-term goal is the eventual global eradication of the disease by 2040–2050, when the development of new tools such as a malaria vaccine, make that feasible. To reach this goal, the interim targets of the Global Malaria Action Plan are to:

- Achieve universal coverage of at-risk populations with a package of malaria prevention and treatment measures by December 2010 and sustain those interventions until country-level evidence suggests that coverage can be gradually reduced without risking a resurgence of disease;
- Reduce the worldwide number of malaria cases by 50 percent in 2010 and by 75 percent in 2015 when compared with 2000 levels;
- Reduce worldwide malaria deaths from 2000 levels by 50 percent in 2010 and to near zero by 2015; and
- Support progressive elimination of malaria in additional countries from 2015 through 2030.

The USG Malaria Strategy's long-term vision is to build on the lessons learned and successes in malaria control over the last five years to support the goals and targets of the Global Malaria Action Plan. In partnership with host countries, other major donors, such as the Global Fund, the World Bank, the private sector, and nongovernmental and community-based organizations, the USG expects to reach the following milestones:

- By 2015, achieve near-universal coverage of populations at risk of malaria in the 15 original PMI countries with highly-effective malaria prevention and treatment measures. This should result in a 70 percent reduction in malaria burden (illnesses and deaths) in those countries, when compared with the PMI baseline established in 2006–2007. At the same time, the USG will expand malaria control efforts to large areas of Nigeria, DRC, which together account for one-half of all malaria in sub-Saharan Africa, and up to seven additional high-burden countries with a goal of a 50 percent reduction in malaria illnesses and deaths when compared to 2009–2010 baselines;
- Between 2015 and 2020, assist Southern Africa Development Community (SADC) countries to create a malaria-free zone in southern Africa through the elimination of transmission in four of those countries;
- Between 2015 and 2030, sustain control efforts in the USG-supported countries across Africa, contributing to the progressive creation of malaria-free zones in East, West, and Central Africa. Achieving this milestone will depend on the control of malaria in both Nigeria and DRC, since those two countries account for such a large proportion of all malaria cases in Africa and they share borders with many other countries that are much farther along in their malaria control efforts. For example, DRC alone has common borders with five PMI countries, three of which are already showing significant reductions in under-five childhood mortality;
- Continue to support work to contain the spread of multidrug-resistant malaria in the Mekong and Amazon Regions, with the long-term goal of elimination of *falciparum* malaria, the most severe form of the disease, from those areas; and
- Demonstrate country ownership to prevent and control malaria morbidity and mortality through strong NMCPs with predictable funding and the staff and technical capabilities to implement and oversee national malaria control efforts.

### Responding to Reductions in the Levels of Malaria Transmission

Significant progress in reducing malaria-related illnesses and deaths is already being seen in a number of the 15 PMI focus countries and additional progress can be expected in the coming years as major increases in coverage of malaria prevention and treatment measures are achieved and sustained. Under the USG Malaria Strategy and in collaboration with other donors and the host countries, reductions in malaria burden will be achieved and sustained through universal

coverage of vector control interventions with improved diagnosis and prompt treatment of malaria infections with safe and highly effective ACTs.

As malaria transmission falls, the use of accurate laboratory diagnosis of infections should increase to ensure that antimalarial drugs are appropriately used and resurgences of malaria are promptly detected. The USG will continue its efforts to expand, strengthen, and improve the quality of malaria microscopic diagnosis in health facilities with laboratories and the use of rapid diagnostic tests for malaria in lower-level health facilities, the private sector, and at the community level.

Malaria transmission may fall heterogeneously within a country, leaving pockets with a significant burden while other areas are nearly free of disease; it is essential therefore to have a well-functioning NMCP that is able to adjust quickly and effectively to changing epidemiologic situations. For this reason, the USG Malaria Strategy will continue to invest in strengthening national capacity for malaria control at central, provincial, and peripheral levels. Valuable lessons also can be learned from experiences in other regions of the world, such as Asia and the Americas, where malaria transmission was reduced to very low levels in the 1970s and 1980s.

As malaria transmission declines, changes in approach to malaria prevention and treatment will also be necessary. For example, the role of IPTp may need to be reexamined. Indoor residual spraying will need to be targeted better to areas where transmission persists at moderate to high levels. With scaled-up prevention measures and improved laboratory diagnosis of malaria, the number of malaria treatments can be expected to decline, but the importance of identifying and appropriately treating other causes of fever will increase. While these changes should result in some savings in the cost of malaria control interventions, the costs of detecting and dealing effectively with resurgences of malaria are likely to increase. Assuming that Global Fund support to malaria control efforts continue at the same or increased levels, it should be possible to gradually reduce USG funding to some of the original 15 PMI countries and apply these savings to support increased efforts in newer focus countries.

## **Malaria Elimination and Eradication**

In sub-Saharan Africa, over the near-term, regional or national malaria elimination may only be possible in selected geographic settings such as islands. In the rest of sub-Saharan Africa, the USG remains committed to aggressive malaria control through the rapid scale-up of proven interventions and the development and use of new technologies that will continue to reduce transmission toward an ultimate goal of malaria eradication. These scale-up efforts will directly contribute to decreasing the malaria burden in endemic areas such that countries or regions within countries might enter the pre-elimination phase. Over the six years covered by this Strategy (2009–2014), the focus of the USG Malaria Strategy in sub-Saharan Africa will be to eliminate malaria as a cause of mortality and reduce transmission and malaria-related illnesses to very low levels.

In the Mekong Region and the South America, where transmission levels are already far lower, the USG will support the elimination of *P. falciparum* malaria as part of the effort to contain multidrug resistance. As part of that investment, the USG will remain closely engaged with working groups pursuing malaria elimination. In addition, the USG will contribute to the rigorous evaluation of malaria programs that have achieved near total cessation of malaria transmission, and review the experience with other successful disease elimination and eradication efforts in order to provide lessons learned.

## PMI'S ROLE IN THE GLOBAL HEALTH INITIATIVE

The GHI represents a USG-wide commitment to work with host governments and other multilateral partners and donors to improve global health in a holistic and sustainable fashion. The GHI builds upon the successes of PMI, PEPFAR, and USG-supported tuberculosis efforts and will carry those commitments forward to 2014. It will help expand PMI activities to reach approximately 70 percent of the malaria at-risk populations in sub-Saharan Africa by the end of the initiative.

The USG Malaria Strategy and PMI will contribute to the core principles of the GHI in the following ways:

### **Woman-Centered Programming**

As a part of the Global Health Initiative, PMI will work to ensure that women remain at the center of USG-supported malaria prevention and treatment activities during the next six years. Pregnant women, along with children under five are the two groups most vulnerable to the effects of malaria and, consequently are the targets of most malaria prevention measures. In most families, women play the major role in deciding where and when young children will seek treatment for illnesses. Women are also in a position to play a key role in promoting behavior change related to the use of LLINs, malaria therapy, and IRS. The PMI will work with ministries of health to involve their reproductive health and maternal and child health departments in the development of the annual PMI operational plans and promote closer working relationships between NMCPs and these departments on malaria-related activities. The PMI will also explore ways to include malaria-related prevention and treatment messages within basic education programs.

### **Strategic Integration and Coordination**

Maternal and child health services: Under PMI, malaria prevention and control activities have been implemented as part of integrated maternal and child health services and make a significant contribution to strengthening capacity to deliver these services. Insecticide-treated nets are distributed principally through antenatal care and child health clinics or through integrated campaigns that include other interventions, such as vitamin A supplementation or vaccinations. Intermittent preventive treatment of pregnant women (IPTp) is a key element of antenatal care, and antimalarial drugs are provided as part of antenatal and child health services. This approach will continue under the USG Malaria Strategy for 2009–2014. The PMI will work with ministries of health to involve their reproductive health and maternal and child health departments in the development of the annual PMI operational plans and promote closer working relationships between NMCPs and these departments on malaria-related activities. In addition, PMI will support integrated management of childhood illness programs, implementation of community-based treatment of fever in which childhood pneumonia, malaria, and diarrhea are diagnosed and treated by trained community health workers, and Focused Antenatal Care programs, which deal broadly with a comprehensive package of services for pregnant women during antenatal clinic visits.

Coordination of malaria and HIV/AIDS service delivery: PEPFAR and PMI currently have eleven focus countries in common (Angola, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Rwanda, Tanzania, Uganda, and Zambia). With the expansion of malaria control activities to additional countries under the USG Malaria Strategy for 2009–2014, this list will grow. Successful collaborations between PMI and PEPFAR around LLIN distribution campaigns, strengthening laboratory diagnostic services, and large-scale household surveys have already occurred, and opportunities will be sought to expand this collaboration during the next five years. In addition, over the next six years, PMI and PEPFAR will work to achieve the following:

- Increased integration of health system functions, including strengthening of pharmaceutical management systems, health management information systems, and laboratory diagnostic services;
- The delivery, where appropriate and supportive country policies exist, of packages of community-based services that include both management of fever and HIV/AIDS prevention;

- Increased integration of prevention of mother-to-child transmission, antenatal care, and malaria in pregnancy; and
- Increased integration, where appropriate, of behavior change communication activities.

Where applicable and cost-effective, PMI and PEPFAR will also work to integrate health system and service delivery efforts with other disease control programs such as for tuberculosis and neglected tropical diseases.

### **Coordination and Multilateral Collaboration**

Partnerships are at the heart of the USG Malaria Strategy for 2009–2014. Achieving the ambitious targets for coverage of major malaria interventions and reductions in malaria burden proposed above only can be achieved through a coordinated approach with a broad partner base, both at country and international levels. The USG works closely with host country governments and supports their national malaria control strategies and plans. The PMI has been a major partner in the RBM Partnership since it was created in 1998 and has been critical in helping to define and focus Partnership efforts. During the next five years, the USG will:

- Continue to play a key role in RBM Partnership working groups on case management, malaria in pregnancy, vector control, procurement and supply management, monitoring and evaluation, and harmonization between partners;
- Maintain close working relationships with major multilateral partners, such as WHO, UNICEF, the World Bank, and the Global Fund, as well as private sector groups involved in malaria control;
- Fill gaps in life-saving commodities, through mechanisms such as PMI’s emergency commodity fund;
- Continue partnering with nongovernmental and faith-based organizations, which often have strong health service delivery programs at the community level, where the impact of malaria is greatest; and
- Coordinate with the Office of Foreign Disaster Assistance on issues related to malaria in complex emergency situations.

### **Host-Country Ownership and Partnership**

Since PMI was launched in June 2005, lessons learned from PEPFAR have helped guide PMI’s approach to ensuring country ownership of malaria control activities. Annual PMI needs assessments and planning visits are carried out with NMCPs and their international and in-country partners. In line with the principles of the “Three Ones,” annual PMI Malaria Operational Plans directly support national malaria control strategies, and PMI program objectives and targets are aligned with those of the host country. Additionally, PMI works with NMCPs to develop costed malaria monitoring and evaluation plans to which all partners can contribute. With the reductions in malaria burden in many countries across Africa, PMI will work with NMCPs to revise and update their malaria control plans.

### **Health Systems Strengthening, Capacity Building, and Sustainability**

Given the high burden malaria imposes on overstretched health systems, malaria control provides an important platform on which to base additional efforts to strengthen these systems. Across malaria-endemic countries in Africa, an average of 25–35 percent of all outpatient clinic visits are for clinically diagnosed malaria. In these same countries, between 20–45 percent of all hospital admissions are caused by malaria. Due to late presentation at a health facility, inadequate clinical management, and frequent unavailability of effective drugs, case fatality rates among hospitalized malaria patients range from 15–35 percent among all age groups. Where effective malaria control has been achieved in high-burden areas, this has resulted in fewer outpatient clinic visits and a dramatic reduction in hospitalizations for malaria. This “unburdening” of the health system frees up health care workers and hospital beds, creating opportunities for the health care systems to function more efficiently.

During the past four years, PMI has supported the sustainability of its programs by strengthening health systems and building the capacities of public and private sector health workers and managers. All PMI activities directly support national malaria control strategies and plans and are implemented with national ministries of health. The USG Malaria Strategy for 2009–2014 will continue this approach, with the long-term goal of ensuring that the gains achieved with USG and other donor support can be sustained. While the focus will remain on malaria, PMI will work to:



- Improve forecasting, procurement, quality control, storage, and distribution of medicines;
- Strengthen disease surveillance and reporting and program monitoring and evaluation within ministries of health;
- Improve service delivery by integrating malaria prevention and treatment activities with other disease control and maternal and child health programs;
- Help build host country managerial and technical capacity related to malaria control;
- Improve the quality of laboratory diagnostic services; and.
- Support capacity development to train malaria leaders.

As part of its investments in health systems strengthening, the USG will track and measure improvements in the functioning of key health systems (e.g., pharmaceutical management systems, health management information systems) at the country level using a competency based index already being employed by PMI.

### **Improved Monitoring, Metrics, and Evaluation**

Careful monitoring and evaluation of malaria control efforts will be critical to continue documenting the progress and success of global malaria control efforts. Coverage of major malaria interventions will be monitored through nationwide household surveys. The impact of USG and partner efforts will be measured by following changes in all-cause mortality in children under five and by following changes in the prevalence of malaria infections and severe anemia, which is closely associated with malaria in young children.

During the next five years, PMI will continue its close coordination with NMCPs and national and international partners. The PMI will work through the RBM Monitoring and Evaluation Reference Group to standardize data collection and reporting using internationally accepted indicators. As part of this effort, PMI will continue to support host country efforts to develop costed national malaria monitoring and evaluation plans, build and strengthen national and provincial/district-level capacity in monitoring and evaluation, including routine data collection systems for health, passive and active malaria surveillance, data analysis, and use of data for decision making. In keeping with the Lantos/Hyde Act, CDC will advise the U.S. Global Malaria Coordinator on monitoring, surveillance, and evaluation activities and be a key implementer of these activities.

To evaluate whether the mortality reduction goals have been achieved, PMI will examine trends in all-cause child mortality, malaria parasitemia, and severe anemia, coverage of malaria control measures (e.g., LLIN, IRS protection) and other factors influencing all-cause child mortality (e.g., vaccination coverage) and malaria-specific mortality (e.g., rainfall). These trends will be used to establish whether mortality has decreased and whether mortality reductions can be attributed to programmatic efforts. Mathematical models will be used to assist in quantification of the reductions in malaria-specific mortality. PMI will not try to attribute increases in coverage of malaria interventions or reductions in malaria morbidity and mortality to USG-supported efforts alone. Instead, PMI will measure progress toward achieving national and international goals and targets that result from the combined efforts of host country governments and other partners involved in malaria control in that country.

As malaria transmission declines, PMI will help build national capacity for malaria surveillance at the health facility level, and using experience gained in Asia and South America, surveillance will be expanded to community health workers. At the same time, district health teams need to have the capability to respond in a timely fashion, so that any resurgences of malaria can be rapidly contained. With the threat of parasite resistance to antimalarial drugs or anopheline mosquito resistance to insecticides, PMI will also assist countries in establishing systems for routine monitoring of antimalarial drug and insecticide resistance.

## **COORDINATING USG MALARIA RESEARCH EFFORTS**

Research is essential to the development and deployment of malaria control tools throughout the malaria endemic world. The USG has for many years played a leading role in supporting and conducting research to develop and test malaria control interventions, including IRS, LLINs, IPTp and ACTs, as well as research and development of new prevention and treatment tools, such as malaria vaccines and new antimalarial drugs. In the future, it will be critical to maintain the USG's strategic role in both basic and applied research related to malaria control.

The Lantos/Hyde Act directs the U.S. Global Malaria Coordinator to ensure that the operational and implementation research supported by under this Act is complementary to research conducted by the National Institutes of Health. This will be accomplished through regular meetings of representatives of HHS, National Institutes of Health, CDC, Department of Defense, and USAID to coordinate research agendas and activities. The Act also directs CDC to advise the U.S. Global Malaria Coordinator on operations research priorities and to be a key implementer of this research.

Under the Lantos/Hyde Act, the focus of malaria research will be on answering operational questions of importance to the implementation of malaria prevention and treatment activities of the Initiative. Many of these questions are related to the use and cost-effectiveness of malaria control measures individually and in combination and will include efforts to establish the best mix of interventions at differing levels of transmission. Interventions that operate in similar fashions, such as IRS and LLINs, may be synergistic, antagonistic, or duplicative. Other interventions, such as IPTp in pregnant women and antimalarial drug treatment without diagnostic confirmation, may be appropriate in settings of high malaria transmission, but no longer cost-effective when transmission falls to low levels. With reductions in malaria transmission, opportunities will also arise to monitor changes in the economic impact of malaria.

As new or improved malaria interventions are developed, operational research will be required to see how best they can be incorporated into USG malaria activities. Understanding how well and under what conditions these tools work will be critical to guiding cost-effective and technically sound decisions. Currently, malaria control program managers and their donor partners aim for high-level coverage of all interventions, but as these goals are attained, they face decisions about where and when to scale back. Without operational research, there will be little knowledge or experience to guide such decisions. These operational research activities will also provide excellent opportunities for mentoring and building capacity among host country public health workers and scientists.

USAID will continue its support to malaria vaccine development and research through the Malaria Vaccine Initiative and for antimalarial drug discovery and development through Medicines for Malaria Venture.

It is expected that existing NIH, CDC, and Department of Defense efforts to develop and test new malaria prevention and control tools, such as new antimalarial drugs, insecticides, and malaria vaccines, as well as to train qualified malariologists, entomologists, and malaria researchers will be continued under those agencies' intra- and extramural research programs. These efforts will complement the implementation research to be carried out under the Lantos/Hyde Act.

## **PMI GOVERNANCE AND MANAGEMENT**

The 2008 Lantos/Hyde Act establishes “within the United States Agency for International Development a Coordinator of United States Government Activities to Combat Malaria Globally (Malaria Coordinator).” The Malaria Coordinator “shall coordinate the provision of assistance by working with relevant executive branch agencies, including the Department of State (including the Office of the Global AIDS Coordinator), the Department of Health and Human Services, the Department of Defense, and the Office of the United States Trade Representative; and relevant multilateral institutions, including the World Health Organization, the United Nations Children’s Fund, the Global Fund, the World Bank, and the Roll Back Malaria Partnership.” For each PMI focus country, an interagency country team composed of USAID and CDC staff will develop a detailed one-year implementation plan describing planned activities, expected results and required budget, based on the national malaria control plan and the experience and results of the previous year’s activities. The first year’s plan will include a five-year strategy.

The USG Malaria Strategy places a premium on tracking how the Initiative’s resources are used; transparency in the way priorities are set and decisions made at the country level; involving other stakeholders; and achieving and documenting results. The Program’s management plan stresses:

- Early obligation of congressionally-appropriated funds so that nearly 100 percent of funds are obligated within the same fiscal year with approximately 30 percent obligated during the first quarter of that year;
- Close management of financial pipelines and routine tracking and review of all activities;
- Minimizing lead times for procurement of critical commodities and services;
- Flexibility in working with other donors to fill gaps in core malaria commodities and services, such as funding the distribution of LLINs procured by other partners;
- Maintaining a central emergency procurement fund to help ensure that no country experiences a stock-out of essential commodities each year; and
- Tracking progress toward the Initiative’s goals and objectives.

### **Accountability**

The PMI has placed a high priority on accountability and transparency. All annual country-level malaria operational plans, the USG Malaria Strategy for 2009–2014, and malaria programmatic and technical guidance documents are posted on the Initiative’s website (<http://www.pmi.gov>), once they are approved by the U.S. Global Malaria Coordinator. In addition, all major contracts and agreements related to malaria activities are posted on the web.

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